

Job description

Job title	QC Microbiologist
Division	Quality
Career Level	CL4
Responsible to	First Line Manager

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized company performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The Company carries out the manufacture of Erwinase® and Anthrax Vaccine as well as contract manufacturing projects.

The Environmental Monitoring Team is a Unit of the Quality Control (QC) Microbiology Department within Porton Biopharma Ltd, based at Porton Down, Wiltshire and supports the GMP manufacture of human Anthrax Vaccine and the anti-cancer treatment, Erwinase.

JOB SUMMARY

To undertake and perform microbiological QC analyses including Environmental Monitoring in support of Porton Biopharma's licensed production, service, validation and developmental programmes.

Communication and key working relationships

Internal

- QC Microbiology Managers
- Production Unit and Functional Managers and staff
- QC Senior/ Microbiologists, Technicians
- Qualified Persons
- Quality Assurance Compliance Officers
- Emcor staff

External

- The Medicines and Healthcare Regulatory Agency (MHRA) Inspectors
- Food and Drug Administration (FDA) Inspectors
- Any other regulatory inspectors
- PBL customers, contractors, suppliers

MAIN DUTIES AND RESPONSIBILITIES

- Operate in compliance with cGMP.
- Train, plan and qualify all Production and other staff, as necessary, in the techniques and procedures for microbiological environmental monitoring and aseptic technique, water sampling and gowning qualifications/ requalification's.
- Oversee, supervise and observe Production and other staff undertaking environmental monitoring and water sampling to ensure continued compliance.
- Perform environmental monitoring when required.
- Perform microbiological testing on water, in process and finished product when required.
- Carry out and record microbiological environmental monitoring for critical manufacturing operations, and routine monitoring where required.
- Input microbiological environmental monitoring and water sampling data into appropriate databases and spreadsheets when required
- Be involved in the writing and updating of Standard Operating Procedures relating to environmental monitoring and water sampling, either as the author, or by providing technical information and advice to the author.
- Attend training courses that contribute to the efficiency of the operating systems and are beneficial to the post holder's personal development.
- Follow operating procedures at all times and ask for advice when necessary.
- Undertake all work in accordance with Porton Down's Code of Safety Practice and Quality Systems.
- To prepare environmental summary reports of production processes for insertion into documents, reports and batch manufacturing records as part of batch release.
- To investigate out-of-specification water and environmental monitoring test results in conjunction with the Compliance Team and review resulting Non-Conformances, participating in Ishikawa and 5-Whys investigations, where necessary.

Other

The above is only an outline of the tasks, responsibilities and outcomes required of the role. You will carry out any other duties as may reasonably be required by the directorate.

The job description and person specification may be reviewed on an ongoing basis in accordance with the changing needs of the organisation.

Professional development

You should pursue a programme of continuous professional development in accordance with any relevant professional registration or statutory requirements, while maintaining appropriate awareness of service provider requirements.

You should adhere PBL values and behaviors:

- Passion; Respect; Integrity; Diligence; Excellence in Execution

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	<input checked="" type="checkbox"/>	
A good standard of written and spoken English Language	<input checked="" type="checkbox"/>	
Qualification		
HND or equivalent qualification relevant to the post	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Degree in a scientific discipline relevant to the post	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Knowledge and experience Experience as defined by type/level (not length)		
Knowledge and experience of microbiology gained in a laboratory, environmental monitoring or similar environment	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Experience of working in a Good Manufacturing Practice (GMP) or similarly regulated environment	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Skills and capabilities		
Accurate and clear record keeping and ability to work to written procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Good interpersonal skills and able to work as part of a team	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Methodical and reliable approach to tasks and ability to think clearly	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ability to respond to sudden and unexpected demands and schedule changes	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ability and willingness to learn	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ability to train others	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Numeracy and writing skills	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Additional Requirements		
Must be prepared to work flexibly to meet the testing requirements of Production schedules, including outside of normal hours and at weekends. To participate in the weekend rota to cover 7 day manufacture	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Must be prepared to receive relevant vaccinations, if required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Must be able to comply with DEFRA SAPO regulations	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Equality and diversity		
An understanding of and commitment to equality of opportunity and good working relationships, both in terms of day-to-day working practices, but also in relation to management systems	<input checked="" type="checkbox"/>	

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	